

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

Groth & Co.KB
Box 6107
102 32 Stockholm

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

02 -12- 2004

Applicant's or agent's file reference
P 04-129/S

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/SE 2004/000636

International filing date (day/month/year)
26 -04 -2004

Priority date (day/month/year)
-

International Patent Classification (IPC) or both national classification and IPC
A61N 1/365, A61N 1/37, A61B 5/021

Applicant

St. Jude Medical AB et al

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/SE
Patent- och registreringsverket
Box 5055
S-102 42 STOCKHOLM
Facsimile No. +46 8 667 72 88

Authorized officer

Anna Malmberg/MN

Telephone No. +46 8 782 25 00

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2004/000636

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing
 table(s) related to the sequence listing

b. format of material

in written format
 in computer readable form

c. time of filing/furnishing

contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.

3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE 2004/000636

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application
 claims Nos. 13-20

because:

the said international application, or the said claims Nos. 13-20
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

The claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. _____

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form has not been furnished
 does not comply with the standard

the computer readable form has not been furnished
 does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No. PCT/SE 2004/000636
--

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
------------------	---

1. Statement

Novelty (N)	Claims	<u>1-12</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-12</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-12</u>	YES
	Claims		NO

2. Citations and explanations:

Documents cited in the International Search Report:

D1:EP 0591642 A1
D2:US 6438408 B1
D3:US 5476483 A1
D4:US 2003/0204145 A1
D5: "Diastolic heart failure", Mandinov L. et al.
Cardiovascular research 45 (2000), p. 813-825.

The cited documents represent the general state of the art. The invention defined in claims 1-12 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed implantable medical apparatus for detecting diastolic heart failure by measuring pulse pressure for a predetermined workload situation and comparing the measured pulse pressure with a predetermined reference value. The cited prior art also does not give any indication that would lead a person skilled in the art to the claimed pacemaker comprising an above mentioned implantable medical apparatus and also comprising control means for optimising pacing therapy depending on the result of the comparison. Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-12 is novel and is considered to involve an inventive step. The invention according to claims 1-12 is industrially applicable.